

USSN 09/616,283; Attorney Docket No. VRXB-P01-001

**DRAFT – NOT FOR ENTRY****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  
GOODNOW, et al.

Serial No: 09/616,283

Attorney Docket No. VRXB-P01-001

Filed: July 14, 2000

Art Unit: 1645

For: SYSTEM FOR DETECTING  
BACTERIA IN BLOOD, BLOOD  
PRODUCTS, AND FLUIDS OF  
TISSUES

Examiner: J. Hines

**Proposed claim amendments**

1. (Currently amended) A method for screening for the presence of a clinically relevant amount of bacteria in donor blood or blood product from a donor mammal for transfer into a recipient mammal, comprising: contacting a sample of the donor blood or blood product with a set of pan-generic binding agents, wherein the set of pan-generic binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen and binding agents that specifically bind to a Gram-positive bacterial antigen, detecting binding of the set of binding agents to the sample, wherein binding indicates the presence of a clinically relevant amount of bacteria in the donor blood or blood product and no binding indicates the absence of a clinically relevant amount of bacteria in the donor blood or blood product from the donor mammal, wherein the blood or blood product determined to have an absence of a clinically relevant amount of bacteria is useful for transfer to the recipient mammal.

35. (Newly added) A method for screening for the presence of a clinically relevant amount of bacteria in donor blood or blood product from a donor mammal for transfer into a recipient mammal, comprising: contacting a sample of the donor blood or blood product with a set of pan-generic binding agents, wherein the set of pan-generic binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen and binding agents that specifically bind to a Gram-positive bacterial antigen,

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detecting binding of the set of binding agents to the sample, wherein said method detects bacterial contamination of as little as  $1 \times 10^6$  CFU/ml.

36. (Newly added) A method for screening for the presence of a clinically relevant amount of bacteria in donor blood or blood product from a donor mammal for transfer into a recipient mammal, comprising: contacting a sample of the donor blood or blood product with a set of pan-generic binding agents, wherein the set of pan-generic binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen and binding agents that specifically bind to a Gram-positive bacterial antigen, detecting binding of the set of binding agents to the sample, wherein detection of bacterial contamination of more than  $1 \times 10^6$  CFU/ml renders the donor blood or blood product unsafe for transfer to a recipient mammal.

Handwritten signature: *Don P. Gray*



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